EUROPEAN COMMISSION

Brussels, 25.9.2013
C(2012) 5944 *final*

Dear President,

The Commission would like to thank the Congreso de los Diputados and the Senado for their Reasoned Opinion concerning the amended Proposal for a Directive of the European Parliament and of the Council on the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems {COM (2013) 168 final/2}.

The Commission would like to offer the following comments on the observations raised in the Opinion. First of all, the Commission would like to recall that its original proposal {COM (2012) 84 final} had raised some concerns expressed by the Member States in the Council as well as by two national Parliaments as regards compliance with the principle of subsidiarity.

After the first reading of the European Parliament in February 2013, the Commission adopted its amended Proposal with the precise aim of taking into account the amendments put forward by the European Parliament as well as the concerns expressed by the Member States.

With respect to the observations made by the Congreso de los Diputados and the Senado, in relation to the principle of subsidiarity, the Commission would like to make the following comments.

According to Article 168(7) TFEU health care falls within the competence of Member States:

"Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them."

Mr Jesús POSADA MORENO
President of the Congreso de los Diputados
Floridablanca s/n
E – 28071 MADRID

Mr Pio GARCÍA-ESCUDERO MÁRQUEZ
President of the Senado
Plaza de la Marina Española, 8
E – 28071 MADRID

In its case-law[1] the Court of Justice ruled that "Community law does not detract from the power of the Member States to organise their social security systems (Case 238/82 Duphar and Others [1984] ECR 523, paragraph 16, Case C-70/95 Sodemare and Others [1997] ECR I-3395, paragraph 27, and Case C-158/96 Kohll [1998] ECR I-1931, paragraph 17). Nevertheless, the Member States must comply with Community law when exercising that power."[2] Therefore, internal market rules, amongst others, need to be constantly observed.

National measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems could create barriers to trade within the EU. For example, the exclusion of a medicinal product from reimbursement in a given country could result in its exclusion from a national market as doctors would be less likely to prescribe it. By making the sales of imported products impossible or more difficult than those of domestic products, pricing and reimbursement measures may be used by Member States to protect their national industry.

In its landmark judgments Roussel[3] and Duphar,[4] the Court of Justice established that the measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems must satisfy certain conditions in order to be compatible with the rules of the Treaty. In particular, they should be free of discrimination against imported medicinal products and they must be based on objective and verifiable criteria that are independent of the origin of the products.

Council Directive 89/105/EEC[5] is a codification of the Roussel and Duphar case-law. It is an internal market instrument designed to facilitate the free movement of medicines. It lays down a general procedural framework to ensure the transparency of measures regulating the pricing and reimbursement of medicinal products.

The amended Proposal for a Directive of the European Parliament and of the Council on the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems (COM (2013)168 final/2 of 20 March 2013) as well as COM (2012) 84 final, repealing the Council Directive 89/105/EEC, maintained the spirit of the existing directive.

In the Reasoned Opinion of the Congreso de los Diputados and the Senado it is argued that this proposal infringes the principle of subsidiarity.

In accordance with the principle of subsidiarity (Article 5 TEU), the EU "should act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level". National pricing and reimbursement decisions on medicinal products have a clear transnational impact linked, in particular, to the potential disruption they might cause to the internal market in these products within the EU.

The existing regulatory framework set up by Directive 89/105/EEC raises uncertainty and implementation challenges due to the evolution of the pharmaceutical market and the concomitant development of national cost control policies over the past twenty years. Pricing systems and health insurance schemes are highly complex and specific to each country.

---

[1] Case C-157/99 *B.S.M. Geraets-Smits and Stichting Ziekenfonds VGZ* [2001] ECR I-5473, paras. 44-46
[2] Ibid.
[3] Case C-181/82 *Roussel Laboratoria* [1983] ECR 3849
[4] Case 238/82 *Duphar and others* [1984] ECR 523
[5] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems [1989] OJ L40/8

Despite the broad legal interpretation provided by the Court of Justice, the notion of some procedural transparency provisions based on the current Directive has given rise to different interpretation in Member States so that action by national competent authorities does not provide sufficient guarantees of procedural transparency and legal security for market operators. Therefore, action at EU level is required.

The Proposal maintains the spirit of the existing Directive as it contains only minimal procedural rules, whilst preserving the competence of Member States for organising their pricing and reimbursement systems, as regards the substance of the decisions they take. Therefore, there is no interference with the capacity of the Member States to price the medicinal products, to fix their level and to decide on their inclusion or about the level of inclusion in the scope of the health insurance systems. The proposal does not touch upon the substance of pricing and reimbursement measures, it does not regulate what the Member States can do with regard to the pricing and reimbursement of medicines, but only how they can do it.

Further, the Congreso de los Diputados and the Senado argue that Article 11 limits Member States' capacity to adopt measures to control or promote the prescription of specific medicinal products. The Commission would like to clarify that this article is just a codification of the existing case-law[6] of the Court of Justice, where the Court ruled that public authorities are allowed to offer financial incentives to doctors to prescribe specific named medicinal products belonging to the same therapeutic class but they should comply with the provisions of Directive 89/105/EEC. Therefore, it only imposes an obligation of transparency: in cases where the competent authorities in charge of pricing and reimbursement decide to adopt measures intended to control or promote the prescription of specific named medicinal products (therefore, they have the liberty to decide), these measures should be based on objective and verifiable criteria. The main aim of such obligation is to ensure that in case the competent authorities decide to promote a certain medicinal product, it should be based on transparent criteria so that there should be no arbitrary decision which would favour one product to the detriment of another (both belonging to the same therapeutic group).

This obligation already exists as a result of the case-law of the Court of Justice and the proposal only codifies this obligation. The proposal of the Commission (both the original and the amended one, according to the same wording) refers only to specific named medicinal products and therefore does not apply to categories of products for which a Member State would want to adopt measures intended to control or promote the prescription.

The Congreso de los Diputados and the Senado also state that in a time of economic crisis, measures to limit spending, and measures related to the cost-effectiveness and budgetary implications become increasingly important. The Commission shares this view and would like to underline that this proposal would help competent authorities to tackle the economic difficulties encountered during the crisis: for example, the proposal put forward by the Commission to ensure faster access to generics on the market would generate important savings for the healthcare budgets. The Pharmaceutical Sector Inquiry based on a sample of medicines analysed during the period 2000-2007 demonstrated that it took more than seven months (on a weighted average basis) for generic entry to occur once originator medicines lost exclusivity.[7] It concluded that significant additional savings could be attained, in case of

---

[6] Case C-62/09 *Association of the British Pharmaceutical Industry v Medicines and Healthcare Products Regulatory Agency*, [2010] ECR I- I-03603

[7] Commission Communication on the Pharmaceutical Sector Inquiry, COM(2009)351, Section 2.1.2; Staff Working Document, SEC(2009)952, §191 et seq.

earlier entry into the market of these products.[8] *Therefore, it is important to look at the broader picture of the benefits which this proposal could bring for patients, national budgets and for the industry.*

The Commission hopes that these clarifications address the concerns raised in the Reasoned Opinion of the Congreso de los Diputados and the Senado and looks forward to continuing our political dialogue in the future, in order to achieve a positive outcome on this important file.

Yours faithfully,

Maroš Šefčovič
Vice-President

[8] Commission Communication on the Pharmaceutical Sector Inquiry, COM(2009)351, Section 2.1.2; Staff Working Document, SEC(2009)952, §217.